

EXHIBIT K

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Konstantin Walmsley, M.D.

1 - - -
2 I N D E X
3 - - -

4
5 Testimony of: KONSTANTIN WALMSLEY, MD
6 By Mr. Tomaselli 7, 125
By Mr. Orent 118

7
8 - - -
9 E X H I B I T S
10 - - -

11	NO.	DESCRIPTION	PAGE
12			
13	Walmsley-1	Rule 26 Expert Report of Konstantin Walmsley, MD	9
14			
15	Walmsley-2	Curriculum Vitae	19
16			
17	Walmsley-3	Surgeon's Resource Monograph, Bates stamped ETH.MESH.10027307 through ETH.MESH.10027328	66
18			
19	Walmsley-4	Gynecare TFT SECUR System IFU, Bates stamped ETH.MESH.02340568 through ETH.MESH.02340590	71
20			
21			
22			
23			
24			

Konstantin Walmsley, M.D.

1	Walmsley-5	Article entitled "A	97
		clinical and	
2		urodynamic study	
		comparing the Stamey	
3		bladder neck	
		suspension and	
4		suburethral sling	
		procedures in the	
5		treatment of genuine	
		stress incontinence"	
6		by Hilton	
7	Walmsley-6	Article entitled	99
		"Comparison of Burch	
8		and Lyodura Sling	
		Procedures for Repair	
9		of Unsuccessful	
		Incontinence	
10		Surgery," by	
		Enzelsberger, et al.	
11			
	Walmsley-7	Article entitled	100
12		"Burch	
		Colposuspension	
13		versus Fascial Sling	
		to Reduce Urinary	
14		Stress Incontinence,"	
		by Albo, et al.	
15			
	Walmsley-8	Article entitled "A	104
16		randomised controlled	
		trial comparing two	
17		autologous fascial	
		sling techniques for	
18		the treatment of	
		stress urinary	
19		incontinence in	
		women: short, medium	
20		and long-term	
		follow-up" by	
21		Guerrero, et al.	
22			
23			
24			

Konstantin Walmsley, M.D.

1 Walmsley-9 AUA Position 111
Statement on the Use
2 of Vaginal mesh for
the Surgical
3 Treatment of Stress
Urinary Incontinence
4 (SUI)

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- - -

DEPOSITION SUPPORT INDEX

- - -

Direction to Witness Not to Answer

Page Line

Request for Production of Documents

Page Line

Stipulations

Page Line

Question Marked

Page Line

Konstantin Walmsley, M.D.

1 - - -

2 KONSTANTIN WALMSLEY, MD,

3 after having been duly sworn, was

4 examined and testified as follows:

5 - - -

6 EXAMINATION

7 - - -

8 BY MR. TOMASELLI:

9 Q. Are you ready to proceed,
10 Dr. Walmsley?

11 A. Yes, sir. Just logging off
12 of my computer here.

13 Q. Do you want to give that a
14 minute?

15 A. Certainly. Yeah.

16 - - -

17 (A discussion off the record
18 occurred.)

19 - - -

20 BY MR. TOMASELLI:

21 Q. Will you please state your
22 name for the record.

23 A. Konstantin Walmsley.

24 Q. Are you a medical doctor?

1 A. I am.

2 Q. What kind of medical doctor?

3 A. I'm a urologist.

4 Q. Okay. My name is Joe

5 Tomaselli, and I'm here representing

6 Ethicon. We're going to talk generally

7 about the TVT SECUR device and other

8 stress urinary incontinence procedures.

9 Okay?

10 A. Yes.

11 Q. If you don't understand any

12 of my questions, just let me know and

13 I'll be happy to rephrase it, but if you

14 answer, I'll assume that you understood

15 it. Okay?

16 A. Okay.

17 Q. Are you being compensated

18 for your time here today?

19 A. I am.

20 Q. And at what rate?

21 A. \$500 an hour.

22 Q. And what did you do to

23 prepare for your deposition today

24 regarding the TVT SECUR?

1 A. Well, there's a wealth of
2 documents and literature I've reviewed.
3 As you know, I've provided expert reports
4 on individuals who have undergone
5 midurethral sling placement and had
6 complications.

7 Q. Okay. And how many TVT
8 SECUR devices have you ever implanted?

9 A. I have never implanted a TVT
10 SECUR device.

11 Q. I'm going to mark as
12 Deposition Exhibit Number 1 -- withdrawn.

13 - - -

14 (Deposition Exhibit No.
15 Walmsley-1, Rule 26 Expert Report
16 of Konstantin Walmsley, MD, was
17 marked for identification.)

18 - - -

19 BY MR. TOMASELLI:

20 Q. Dr. Walmsley, I'm marking as
21 Deposition Exhibit Number 1 your general
22 report that was provided to me.

23 Can you confirm that that's
24 what that is?

1 A. Yes. This is it.

2 Q. And that report has two
3 general opinions in it; is that right?

4 A. That's correct.

5 Q. And general opinion number 1
6 relates to the instructions for use for
7 the TVT SECUR?

8 A. Yes.

9 Q. And the last paragraph of
10 general opinion number 1 states that it's
11 your, Dr. Walmsley's, opinion that "the
12 IFU for the TVT-Secur in 2010 was not
13 sufficient to enable informed consent
14 from the patient."

15 Do you see that?

16 A. Not in the last paragraph.

17 Q. I'm sorry, my bad. It's the
18 last paragraph above the word "Adverse
19 Reactions."

20 A. Yes, sir. Yes.

21 Q. Okay. And it is, indeed,
22 your opinion and an opinion that you're
23 rendering today as of 2010. Right?

24 A. Correct.

1 Q. Does the instructions for
2 use go to the patient?

3 A. It's accessible to the
4 patient.

5 Q. Okay.

6 A. But whether it goes to the
7 patient or not, I don't believe so.

8 Q. And who is the IFU intended
9 for?

10 A. It's intended for the
11 clinician.

12 Q. The surgeon that's
13 implanting the device?

14 A. Yes.

15 Q. Dr. Walmsley, with respect
16 to general opinion number 1 and your
17 statement that "the IFU for the TVT-Secur
18 was not sufficient to enable informed
19 consent" to "the patient, is that opinion
20 with respect to the fact that the
21 document alone, the IFU for the TVT SECUR
22 alone, does not contain all the
23 information that you think it should?

24 A. I'm not sure I understand

1 your question. I'm sorry.

2 Q. Okay. Is your opinion that
3 the TVT SECUR IFU was not sufficient, is
4 that opinion in isolation to the TVT
5 SECUR IFU, or does it also encompass all
6 of the training or experience that a
7 physician might otherwise have? Did you
8 understand my question?

9 MR. ORENT: Objection.

10 THE WITNESS: I understand
11 your question. And I would say not
12 specifically in isolation.

13 BY MR. TOMASELLI:

14 Q. Okay. So as part of general
15 opinion number 1, you are considering the
16 information that a physician implant
17 might bring to the table before using
18 that device?

19 MR. ORENT: Objection,
20 vague.

21 THE WITNESS: Well, once
22 again, yeah, I'm trying to understand
23 what specific information you're
24 alluding to.

1 BY MR. TOMASELLI:

2 Q. Well, I guess what I'm
3 asking you is, is whether your opinion is
4 that the TVT SECUR instructions for use
5 is not adequate just in isolation, just
6 picking up a document and reading it.
7 You're saying that's not enough. Or
8 whether it is given the information that
9 I have, even Dr. Walmsley over my career,
10 me picking up the IFU for the TVT SECUR,
11 it's still not adequate. Does that make
12 sense?

13 MR. ORENT: Objection.

14 THE WITNESS: Somewhat.

15 BY MR. TOMASELLI:

16 Q. Okay. And I guess so my
17 question is, are you really saying that
18 the IFU itself, that, you know, without
19 regard to other information I may or may
20 not have, if I just picked up this piece
21 of paper, this is insufficient by itself?

22 A. See, part of the difficulty
23 in answering that question -- and you've
24 probably seen this as well -- is that

1 IFUs change over time. IFUs will add or
2 perhaps delete adverse events or
3 precautions. So as a physician, as an
4 implanting surgeon, we lend a certain
5 amount of weight in terms of reading an
6 IFU and extracting from that what is the
7 risk/benefit analysis for this particular
8 patient as it relates to implanting this
9 device.

10 There may be information we
11 derive at cadaveric workshops. There may
12 be information that we derive from our
13 partners, our colleagues, from key
14 opinion leaders that we rely upon and
15 trust in terms of selecting the proper
16 patient or perhaps in the surgical
17 technique itself. But it's all premised
18 around the foundation of an IFU.

19 Q. Okay. The second general
20 opinion that you have in your report
21 relates to safer alternative designs and
22 procedures existing in 2010 that have a
23 less risk of erosion and dyspareunia with
24 equivalent efficacy.

Konstantin Walmsley, M.D.

1 Do you remember that?

2 A. Correct.

3 Q. All right. And again, that
4 opinion is as of 2010?

5 A. In this particular report,
6 that's correct.

7 Q. All right.

8 A. Yes.

9 Q. And the safer alternative
10 design and procedure that you list in
11 general opinion number 2 is the
12 autologous fascial sling using rectus
13 fascia; is that right?

14 A. Yes.

15 Q. Okay. And in your report do
16 you specifically list any other safer
17 alternative design or procedure other
18 than the autologous rectus fascia?

19 MR. ORENT: Objection.

20 THE WITNESS: The autologous
21 rectal fascia was meant to be an
22 example of a safer alternative design
23 and procedure.

24 BY MR. TOMASELLI:

1 Q. And that's the only one you
2 reference in your report. Right?

3 A. Correct.

4 Q. You go on in general opinion
5 number 2 to say that the patient "was
6 unable to receive proper informed
7 consent" related "to this safer
8 alternative because of the lack of
9 information in the TVT-Secur IFU inherent
10 to the risks of using synthetic mesh as
11 an alternative to autologous fascia."

12 Do you see that?

13 A. I do.

14 Q. All right. Is it your
15 opinion that the TVT SECUR IFU should
16 have contained information regarding
17 autologous rectal fascia and adverse
18 events and compared the two procedures?

19 A. No, it's not.

20 Q. Okay.

21 A. If I could amend that
22 sentence or perhaps make it clearer.

23 Q. Sure.

24 A. I would probably add, for

1 example, as an alternative to using
2 autologous fascia. Inherent to the risks
3 of using synthetic mesh, for example, as
4 an alternative to using autologous fascia
5 or some other safer alternative design
6 and procedure.

7 Q. Okay. And those two general
8 opinions, one related to the TVT IFU and
9 secondly to the safer alternative design
10 as set forth in your report, those are
11 the only two general opinions that you
12 have in this report. Right?

13 A. Yes, sir.

14 Q. Okay. In your report which
15 is Exhibit Number 1, you list a variety
16 of materials reviewed in connection with
17 this report. Right?

18 A. Yes.

19 Q. And those materials are
20 actually typed in and included in the
21 report?

22 A. Yes.

23 Q. All right. Is there a
24 separate document or anything that you

1 have that's not part of this report that
2 has materials reviewed for this case?

3 A. I have a binder of
4 reports -- pardon me -- of papers.

5 Q. Okay. And are those the
6 papers that are referenced in Exhibit 1?

7 A. That's correct.

8 Q. Okay.

9 A. Yes.

10 Q. And can we agree that the
11 materials you reviewed and listed in your
12 report do not include any Ethicon
13 internal memorandums or e-mails or things
14 like that?

15 A. That's correct.

16 Q. All right. And you did not
17 review those in connection with this
18 report; is that right?

19 A. With the exception of just
20 the instructions for use, there's no
21 Ethicon-specific documents or internal
22 documents that are reviewed.

23 Q. And it's also true that you
24 did not review and did not put in your

1 materials reviewed any depositions that
2 may have been taken of Ethicon personnel.
3 Right?

4 A. Correct.

5 Q. I'm going to mark as
6 Deposition Exhibit Number 2,
7 Dr. Walmsley, your curriculum vitae.

8 Is that what that is?

9 - - -

10 (Deposition Exhibit No.
11 Walmsley-2, Curriculum Vitae, was
12 marked for identification.)

13 - - -

14 THE WITNESS: Yes, sir.

15 BY MR. TOMASELLI:

16 Q. You practice at the Urology
17 Group of New Jersey; is that right?

18 A. Yes, sir.

19 Q. And it looks like it's a
20 group of over 20 physicians?

21 A. Correct.

22 Q. And are they all urologists?

23 A. We have one urogynecologist.

24 We have a radiation oncologist. And we

1 have a medical oncologist as well.

2 Q. How many different
3 urologists do you practice with in your
4 group?

5 A. Currently 21, give or take
6 one or two.

7 Q. And do you know any of those
8 urologists, whether they are members of
9 the American Urological Association?

10 A. Yes.

11 Q. And are some of your
12 partners -- and I use the term "partner"
13 generally to speak of the people that you
14 practice with. Okay?

15 A. Yes.

16 Q. I'm not necessarily saying
17 they're some corporate entity. All
18 right?

19 A. Correct.

20 Q. With respect to other of
21 your partners, are any of them members of
22 AUGS, that organization?

23 A. One of them may be.

24 Q. Do you assist your other

1 partners with surgeries if needed?

2 A. Yes.

3 Q. And will they likewise

4 assist you if you need assistance with a

5 particular surgery?

6 A. Yes.

7 Q. Are there doctors in your

8 group other than you that perform stress

9 urinary incontinence surgery?

10 A. Yes.

11 Q. Are there doctors other than

12 you that perform prolapse surgery?

13 A. Yes.

14 Q. Do you, sir, perform

15 prolapse surgery currently?

16 A. Yes.

17 Q. My understanding is that

18 from 1997 to 2003, you performed a

19 urological and general surgery residency

20 at New York Presbyterian Hospital?

21 A. Yes. New York Presbyterian

22 Hospital Cornell.

23 Q. Cornell?

24 A. Yes.

1 Q. And after that, from 2003
2 and 2004 you performed a fellowship at
3 Columbia Presbyterian there in New York
4 in female urology and voiding?

5 A. And voiding dysfunction,
6 yes.

7 Q. Voiding dysfunction?

8 A. Yes.

9 Q. As part of your residency
10 and fellowship, did you receive training
11 with respect to surgery in the pelvic
12 space?

13 A. Yes.

14 Q. Did you receive training on,
15 for example, open procedures as well as
16 laparoscopic procedures?

17 A. That's correct.

18 Q. Did you receive training on
19 stress urinary incontinence surgical
20 procedures?

21 A. Yes.

22 Q. And what types of surgical
23 procedures for stress urinary
24 incontinence were you trained on in your

1 residency and fellowship?

2 A. I performed autologous
3 fascial slings. I performed synthetic
4 mesh-based sling procedures, performed
5 collagen injection procedures and also
6 performed Burch colposuspension
7 procedures or Burch urethral suspension
8 procedures.

9 Q. Were you also trained in
10 your residency and fellowship with
11 respect to prolapse surgery?

12 A. Yes, I was.

13 Q. And can you describe the
14 different prolapse surgeries that you
15 were trained on back in the late '90s,
16 early 2000s?

17 A. Yes. I performed both
18 vaginal and abdominal reconstructive
19 procedures. The abdominal reconstructive
20 procedures I was trained on were
21 sacrocolpopexies. I also performed
22 vaginal reconstructive procedures, the
23 majority of which were native tissue
24 repairs, along with some that utilized

1 biological graft materials.

2 Q. With respect to your
3 training on stress urinary incontinence
4 procedures, were you trained on different
5 routes of using the synthetic mesh
6 slings, such as the transobturator route
7 or the retropubic route?

8 A. The two routes that I
9 utilized in my residency and fellowship
10 were retropubic and suprapubic.

11 Q. Have you subsequently been
12 trained on the transobturator route?

13 A. I learned that in my private
14 practice, yes.

15 Q. And have you ever used that
16 route for patients in your private
17 practice?

18 A. Yes.

19 Q. In terms of the synthetic
20 mesh that you used since 1997, would
21 those be meshes made of polypropylene?

22 A. With the exception of a
23 brief experience with the Mentor ObTape,
24 yes.

1 Q. And in terms of the
2 polypropylene meshes, do you recall which
3 ones that you were trained on and used in
4 your private practice?

5 A. In my private practice?

6 Q. Well, let's split that up.
7 Let's talk about training first, how
8 about.

9 A. Okay. In my training, my
10 exposure was to TVT.

11 Q. Is that the retropubic
12 route?

13 A. Correct.

14 Q. Okay.

15 A. And then in my private
16 practice -- I should also say in my
17 training I utilized a product called
18 SPARC which was an AMS-based product that
19 was a suprapubic approach.

20 In my private practice, I've
21 utilized a variety of different
22 synthetics, retropubic, suprapubic,
23 transobturator, single incision. I've
24 used TVT. I've used Bard's product, both

1 the AJUST and the AJUST's predecessor.

2 If I didn't mention Boston
3 Scientific, I used Boston Scientific
4 materials. I used an AMS sling and also
5 a Coloplast sling.

6 Q. And since 1997, how many
7 times do you think that you've generally
8 implanted a polypropylene midurethral
9 sling for the treatment of stress urinary
10 incontinence?

11 A. Several hundreds. Several
12 hundreds. Somewhere between 3- and 500,
13 I would estimate as a guess.

14 Q. And would you say that
15 you've had good success with the
16 polypropylene midurethral slings in
17 treating stress urinary incontinence?

18 MR. ORENT: Objection.

19 THE WITNESS: Depending upon
20 how one defines success, yes.

21 BY MR. TOMASELLI:

22 Q. Let's talk about in terms of
23 cure rates.

24 Have you had good success in

1 terms of cure rates with the use of
2 polypropylene midurethral slings?

3 A. Fairly good.

4 Q. Is it true that no treatment
5 for stress urinary incontinence is
6 100 percent effective?

7 A. I think that's true.

8 Q. And, indeed, whether we're
9 talking about autologous slings or
10 synthetic slings or any other procedure,
11 those procedures can fail to cure stress
12 urinary incontinence?

13 A. This can happen.

14 Q. And would you agree that the
15 medical community of surgeons performing
16 stress urinary incontinence surgery are
17 aware of the possibility that surgery
18 will not cure the stress urinary
19 incontinence?

20 MR. ORENT: Objection.

21 THE WITNESS: Yes.

22 BY MR. TOMASELLI:

23 Q. Would you say that that's
24 common knowledge?

1 MR. ORENT: Objection.

2 THE WITNESS: I would

3 imagine so.

4 BY MR. TOMASELLI:

5 Q. Do you agree that it's

6 impossible to predict which patients will

7 be cured and which patients won't be

8 cured from a stress urinary incontinence

9 procedure?

10 A. I think that's possible.

11 Q. You think it's possible to

12 predict?

13 A. I do.

14 Q. Have you ever implanted a

15 midurethral sling made of polypropylene

16 when you predicted that it would fail?

17 A. Not to that extent, no.

18 Q. Have you ever implanted a

19 polypropylene midurethral sling when you

20 weren't sure that it would cure their

21 stress urinary incontinence?

22 MR. ORENT: Objection.

23 THE WITNESS: I guess the

24 way I would answer that question is,

1 is to say that I have implanted
2 synthetic midurethral slings expecting
3 better results in certain patients and
4 possibly not as good results in other
5 patients.

6 BY MR. TOMASELLI:

7 Q. All right. You said that
8 when you were trained, you were trained
9 on the TVT Classic retropubic device?

10 A. That's correct.

11 Q. And do you recall how many
12 times that you used that device, just
13 approximately?

14 A. In my fellowship, perhaps 30
15 to 60 times.

16 Q. Have you ever used that --
17 sorry.

18 Have you ever used that
19 device in private practice?

20 A. I have.

21 Q. And would you say that
22 you've had success in terms of cure rates
23 with respect to that device?

24 MR. ORENT: Objection.

1 THE WITNESS: In terms of
2 cure rates, I've been satisfied.

3 BY MR. TOMASELLI:

4 Q. Okay. Have you ever used
5 the TVT obturator device in your private
6 practice?

7 A. I have not.

8 Q. In terms of the obturator
9 route for stress urinary incontinence
10 surgery, which devices, if you can
11 recall, did you use?

12 MR. ORENT: Objection.

13 THE WITNESS: I've used Bard
14 devices, specifically the -- there are
15 two Bard devices that I've used that
16 both are no longer on the market that
17 I've used. There's a Boston
18 Scientific device, an AMS device that
19 I've used, a Coloplast device that I
20 have used and continue to use.

21 BY MR. TOMASELLI:

22 Q. Setting aside the ObTape for
23 a second, okay, would you say that all of
24 the polypropylene midurethral slings that

1 you've used are macroporous?

2 MR. ORENT: Objection.

3 THE WITNESS: Yes. I

4 believe so.

5 BY MR. TOMASELLI:

6 Q. And would you say that they

7 were all lightweight?

8 MR. ORENT: Objection.

9 THE WITNESS: Yes.

10 BY MR. TOMASELLI:

11 Q. Do you know with respect

12 to -- withdrawn.

13 My understanding is that in

14 the last five years or so, you've -- with

15 respect to polypropylene midurethral

16 slings, you've used the Bard ALIGN; is

17 that right?

18 A. That's correct.

19 Q. And you've used products

20 from AMS?

21 A. That's correct.

22 Q. And you've used Coloplast

23 regular length and also their mini as

24 well?

1 A. Correct.

2 Q. Do you know whether those
3 polypropylene midurethral slings are cut
4 mechanically or with a laser?

5 A. I'm not aware.

6 Q. With respect to the
7 Coloplast mini midurethral sling made of
8 polypropylene, did you say that you still
9 use that today or you just started using
10 it? I can't remember.

11 MR. ORENT: Objection.

12 THE WITNESS: I've recently
13 been trained on it.

14 BY MR. TOMASELLI:

15 Q. Okay. And prior to recently
16 being trained on the Coloplast mini
17 sling, did you use mini slings prior to
18 that?

19 A. I did.

20 Q. Okay. And what types were
21 those?

22 A. It was a mini sling made by
23 Contasure, C-O-N-T-A-S-U-R-E.

24 Q. Thank you.

1 A. Uh-huh.

2 Q. Any others?

3 A. No. Just that one.

4 Q. Dr. Walmsley, in your
5 residency and in your fellowship, did you
6 ever have the occasion to see a
7 complication from the implant of a
8 polypropylene midurethral sling?

9 A. Yes.

10 Q. And did you have the
11 occasion to treat those complications?

12 A. Well, I mean, your first
13 question was complication, and then you
14 just asked about complications.

15 Q. Well --

16 A. So as we sit here today, I
17 can only really think of one complication
18 that I specifically treated.

19 Q. Okay.

20 A. Which I think in part
21 relates to the fact that when you're a
22 resident or a fellow, you don't
23 necessarily have that much follow-up with
24 the patients you treat.

1 Q. What complication do you
2 recall seeing as a resident or fellow?

3 A. There was a patient -- I
4 stand corrected. I guess technically
5 there was more than one complication, but
6 the one complication that comes to mind
7 was a patient in my fellowship who I
8 treated with a TVT Classic sling that
9 presented with severe bleeding.

10 Q. Okay. You stated that you
11 also performed the Burch procedure in
12 residency and fellowship?

13 A. That's correct.

14 Q. Did you ever have the
15 occasion to perform the MMK procedure?

16 A. I did not, although I had
17 familiarity with it. I may -- you know,
18 I stand corrected. I may have actually
19 performed an MMK procedure as well. It's
20 been a long time since my residency, and
21 I know the two procedures. For whatever
22 reason, I'm remembering the Burch
23 urethropexy more than the MMK, but
24 there's a strong possibility I've done

1 both.

2 Q. With respect to the
3 midurethral sling procedures, do those
4 involve incisions through the vagina?

5 A. Yes.

6 Q. Do autologous fascia slings
7 involve an incision through the vagina?

8 A. Yes.

9 Q. Do slings made of biologic
10 graft material also involve an incision
11 through the vagina?

12 A. Yes.

13 Q. Does the Burch procedure
14 involve an incision through the vagina?

15 A. Yes.

16 Q. Does the MMK procedure
17 involve an incision through the vagina?

18 A. Yes.

19 Q. Is it -- what is --
20 withdrawn.

21 What is wound dehiscence?

22 A. Wound dehiscence describes a
23 process where there is an area of
24 breakdown or opening of a closure.

1 Q. Closure of an incision?

2 A. An incisional closure,
3 correct.

4 Q. And is that idea different
5 than or synonymous with a failure to heal
6 along an incision line?

7 A. I think a wound dehiscence
8 probably falls as a subset under that
9 category of failure to heal.

10 Q. Okay. And is the risk of
11 the failure of a vaginal incision wound
12 to heal a risk with all stress urinary
13 incontinence procedures?

14 A. Theoretically, yes.

15 Q. And if an incision wound
16 failed to heal, would you call that a
17 failure of the surgery or a failure of
18 the material or procedure used to cure
19 the stress urinary incontinence? Do you
20 understand my question?

21 MR. ORENT: Objection.

22 THE WITNESS: Well, I mean,
23 there are a lot of different moving
24 parts to the question.

1 BY MR. TOMASELLI:

2 Q. Okay. So -- well, I'll just
3 withdraw it.

4 Do you agree that the
5 medical community of surgeons performing
6 stress urinary incontinence procedures
7 are aware of the possibility of the
8 complication of failure to heal at the
9 incision line?

10 A. Yes.

11 Q. When you use the term
12 "erosion" -- well, withdrawn.

13 Dr. Walmsley, there are
14 various terms in these cases related to
15 erosion and extrusion and exposure.

16 Have you heard all those
17 different kinds of terms?

18 A. I have.

19 Q. All right. And I just want
20 to get your understanding of how you
21 would use those terms. So if we can
22 start with erosion first, can you
23 describe if somebody said "I had an
24 erosion of a sling," what would that mean

1 to you?

2 A. That would mean to me that
3 the material -- the sling material eroded
4 through and into an organ or space.

5 Q. And would the organs that a
6 sling of whatever material can erode into
7 be the bladder, the rectum, the urethra
8 and the vagina?

9 A. Yes. Those would be some
10 examples of that. Yeah.

11 Q. Okay. And it's true that
12 biologic grafts made of pig and
13 autologous fascia made of rectus sheath,
14 those can erode into other organs as
15 well. True?

16 A. Very fairly.

17 Q. It can happen?

18 MR. ORENT: Objection.

19 THE WITNESS: I've never
20 seen it in my clinical practice, so...

21 BY MR. TOMASELLI:

22 Q. Okay. But you've seen
23 literature, obviously, stating that you
24 can have erosion, for example, into the

1 urethra with those products?

2 A. There have been a couple.

3 Q. When did you become aware of
4 the possibility that erosion could occur
5 with a polypropylene midurethral sling?

6 A. Well, fairly soon after I
7 started utilizing the material.

8 Q. So you became aware of the
9 potential for erosion for a polypropylene
10 midurethral sling dating back to the late
11 '90s?

12 MR. ORENT: Objection.

13 THE WITNESS: Once again, in
14 the late '90s, I was early in my
15 residency. And I didn't -- you know,
16 as a resident, I was really more
17 involved in the operative side of
18 things than I was in patient
19 follow-up.

20 BY MR. TOMASELLI:

21 Q. Okay. In terms of the
22 timing, then, would you say that you were
23 certainly aware of the possibility that
24 erosion or exposure could occur with a

1 polypropylene midurethral sling by the
2 early 2000s?

3 MR. ORENT: Objection.

4 THE WITNESS: I would say
5 that by 2004 I was aware of that.

6 BY MR. TOMASELLI:

7 Q. Okay. And how did you
8 become aware of the possibility that
9 erosion or exposure could occur with a
10 midurethral sling made of polypropylene?

11 A. Well, two reasons. I mean,
12 one was in my fellowship and early
13 private practice going to workshops where
14 erosion was discussed. And secondly, in
15 terms of reading the IFUs at that time
16 that talked about erosion in a particular
17 context.

18 Q. And when you say that you
19 went to workshops and that was discussed,
20 can you describe what kind of workshops
21 those are?

22 A. Yes. I went to several
23 different cadaveric training workshops
24 where there would be didactic sessions

1 and then labs where you'd operate
2 either -- mostly on human cadavers
3 implanting mesh.

4 And during those
5 conferences, if you will, there were
6 discussions about erosion.

7 Q. Were you also aware of
8 reports, for example, in the medical
9 literature that discussed erosion or
10 exposure of polypropylene midurethral
11 slings into other organs?

12 MR. ORENT: Objection.

13 THE WITNESS: I did have
14 awareness of that.

15 BY MR. TOMASELLI:

16 Q. When did you become aware of
17 the possibility that scarring in the
18 vagina could occur with a surgery for
19 stress urinary incontinence?

20 A. Well, I mean, scarring is a
21 natural phenomenon from any surgery.
22 Whether it's surgery for stress urinary
23 incontinence or removing a kidney tumor,
24 I mean, scarring is the natural process

1 of healing.

2 Q. Okay. When did you become
3 aware of the possibility of pelvic pain
4 or groin pain or suprapubic pain with the
5 use of midurethral slings for stress
6 urinary incontinence?

7 MR. ORENT: Objection.

8 THE WITNESS: Well, I think
9 I'd have to probably answer that
10 question the same as the first.

11 It's -- those terms, "pelvic pain,"
12 "groin pain," those are natural
13 phenomena from a sling procedure,
14 whether it's done -- you know,
15 whatever the material is that's used.

16 BY MR. TOMASELLI:

17 Q. Would you say the same for
18 the possibility of bleeding or infection
19 or a wound complication?

20 A. I would.

21 Q. I want to talk to you for a
22 second about dyspareunia, which is pain
23 with intercourse. Right?

24 A. Yeah.

1 Q. Are there other courses of
2 dyspareunia other than a stress urinary
3 incontinence procedure?

4 A. Yes.

5 Q. Would one of those be
6 vaginal atrophy or atrophic vaginitis?

7 A. That's one, yes.

8 Q. What are some others?

9 A. Prior pelvic surgery,
10 radiation to the pelvis, inflammatory
11 conditions affecting the vulva or the
12 vagina.

13 Q. When you say "prior pelvic
14 surgery," what's in your mind when you
15 say that? Sorry for my legs.

16 A. Oh, hysterectomy. Any sort
17 of pelvic surgery that creates fibrosis
18 or scarring as part of its healing
19 process.

20 Q. Would you agree that new
21 onset dyspareunia is a risk, a potential
22 risk, with all stress urinary
23 incontinence procedures?

24 MR. ORENT: Objection.

1 THE WITNESS: With the
2 exception of collagen injection,
3 there's some truth to that.

4 BY MR. TOMASELLI:

5 Q. Okay. So let's set collagen
6 injection to the side for a second.

7 Would you agree that new
8 onset dyspareunia is a risk with all
9 stress urinary incontinence surgeries?

10 MR. ORENT: Objection. I
11 don't know that you can actually just
12 cherry-pick out to get your quote one
13 of the surgeries. I think his answer
14 is no. And then he answered what
15 surgery you couldn't. And now you're
16 asking him aside from the surgery that
17 can't, are there any surgeries that
18 can. So I don't think that's a proper
19 question.

20 MR. TOMASELLI: All right.
21 Let me start over. And, you know, you
22 can say objection, form, and that will
23 be just fine.

24

1 BY MR. TOMASELLI:

2 Q. Let me start over. Sorry if
3 I was unclear, Doctor.

4 Dr. Walmsley, would you
5 agree that new onset dyspareunia is a
6 risk with all midurethral sling
7 procedures using polypropylene mesh?

8 MR. ORENT: Objection.

9 THE WITNESS: Yes.

10 BY MR. TOMASELLI:

11 Q. Would you agree that new
12 onset dyspareunia is a risk with
13 autologous fascia procedures for stress
14 urinary incontinence?

15 MR. ORENT: Objection.

16 THE WITNESS: To some
17 degree, yes.

18 BY MR. TOMASELLI:

19 Q. And would you provide the
20 same answer with respect to the biologic
21 grafts used for stress urinary
22 incontinence procedures?

23 MR. ORENT: Objection.

24 THE WITNESS: Yes.

1 BY MR. TOMASELLI:

2 Q. And would you provide the
3 same answer with respect to the Burch
4 procedure?

5 MR. ORENT: Objection.

6 THE WITNESS: Yes.

7 BY MR. TOMASELLI:

8 Q. Is it also a possibility,
9 Dr. Walmsley, that dyspareunia that a
10 patient suffers before a procedure for
11 stress urinary incontinence can actually
12 resolve or get better after the
13 procedure?

14 MR. ORENT: Objection.

15 THE WITNESS: I've not seen
16 that before. It depends, obviously,
17 on what the cause of the dyspareunia
18 is pre-procedure. So if there's some
19 sort of concurrent treatment of the
20 cause of the dyspareunia, I suppose
21 that's possible. For example, a
22 cystocele might cause dyspareunia.
23 And if one fixes the cystocele, that
24 might fix the cystocele-induced

1 element of the dyspareunia, for
2 example.

3 BY MR. TOMASELLI:

4 Q. Thank you. Are urge
5 incontinence and overactive bladder
6 symptoms -- well, withdrawn.

7 Can a woman suffer urge
8 incontinence and overactive bladder
9 symptoms in the absence of undergoing a
10 surgical procedure for stress urinary
11 incontinence?

12 A. Yes.

13 Q. All right. Is there a
14 background rate of overactive bladder
15 symptoms in women?

16 A. Background rate? I don't
17 understand that terminology.

18 Q. Sure. So in your practice,
19 I suppose that you have a general female
20 urology practice?

21 A. I do.

22 Q. And are there women that
23 come to you that have overactive bladder
24 symptoms that have never had a stress

1 urinary incontinence procedure?

2 A. Yes.

3 Q. If a woman came to you with

4 overactive bladder symptoms, is that a

5 common thing that you see in your

6 practice, or is that relatively uncommon?

7 MR. ORENT: Objection.

8 THE WITNESS: Fairly common.

9 BY MR. TOMASELLI:

10 Q. And with respect to urge

11 incontinence, I assume you see that in

12 your practice?

13 A. I do.

14 Q. And can urge incontinence

15 occur, again, in the absence of having a

16 stress urinary incontinence procedure?

17 A. Yes.

18 Q. Is it also possible that a

19 woman without urge incontinence can have

20 a new onset of urge incontinence after a

21 surgery for stress urinary incontinence?

22 A. That can happen.

23 Q. Can that happen, that is,

24 new onset urge incontinence, can that

1 happen with any polypropylene midurethral
2 sling surgery?

3 MR. ORENT: Objection.

4 THE WITNESS: Yes.

5 BY MR. TOMASELLI:

6 Q. Can it occur also with
7 surgeries using autologous fascia or
8 biologic grafts?

9 MR. ORENT: Objection.

10 THE WITNESS: To some
11 degree, yes.

12 BY MR. TOMASELLI:

13 Q. Can new onset urge
14 incontinence also occur with the Burch
15 procedure?

16 MR. ORENT: Objection.

17 THE WITNESS: To some
18 degree, yes.

19 BY MR. TOMASELLI:

20 Q. What is urinary retention?

21 A. That is an inability to
22 void, where your bladder becomes
23 overextended.

24 Q. Okay. And can urinary

1 retention occur in women in the absence
2 of a stress urinary incontinence surgery?

3 A. Yes.

4 Q. You see that in your
5 practice?

6 A. I do.

7 Q. And can urinary retention
8 also be associated with any stress
9 urinary incontinence surgery?

10 A. Yes.

11 Q. Can urinary retention be
12 associated, again, with procedures
13 utilizing autologous fascia, for example?

14 A. Yes.

15 Q. Is there a way to predict
16 with women undergoing a procedure for
17 stress urinary incontinence who or who
18 will not potentially have a complication
19 of urinary retention after that surgery?

20 A. To some extent, yes.

21 Q. And what do you think about
22 in terms of -- in that regard?

23 A. I think about patients who
24 are on medications that might otherwise

1 relax their bladder, for example,
2 antidepressants. I think about patients
3 who have stress urinary incontinence in
4 the setting of incomplete bladder
5 emptying or a somewhat weakened bladder.
6 Those are a couple of instances where I
7 point out to a patient that she might
8 have a higher risk of retention following
9 surgery.

10 Q. Okay. When would you say,
11 Dr. Walmsley, that you became aware of
12 the potential for urge incontinence or
13 overactive bladder symptoms or urinary
14 retention? When would you say that you
15 became aware of those potential
16 complications with stress urinary
17 incontinence surgery?

18 A. Fairly early in my
19 experience with them.

20 Q. So would that be -- again,
21 pegging your fellowship being in the
22 early 2000s, would that be a reasonable
23 time?

24 MR. ORENT: Objection.

Konstantin Walmsley, M.D.

1 THE WITNESS: I think that's
2 reasonable.

3 BY MR. TOMASELLI:

4 Q. Dr. Walmsley, do you have
5 any peer-reviewed publications regarding
6 prolapse or stress urinary incontinence
7 surgery?

8 A. I have given grand rounds on
9 the management of both medical and
10 surgical for urinary incontinence, if
11 that answers your question.

12 Q. Okay. Let's break those up
13 real quick if we can.

14 A. Sure.

15 Q. Dr. Walmsley, do you have
16 any peer-reviewed publications pertaining
17 to the management of prolapse or stress
18 urinary incontinence?

19 A. I don't.

20 Q. Do you have any
21 peer-reviewed publications pertaining to
22 the use of mesh with prolapse or with
23 stress urinary incontinence surgery?

24 A. I don't.

1 Q. Dr. Walmsley, have you ever
2 performed grand rounds with respect to
3 the management of stress urinary
4 incontinence?

5 A. I have.

6 Q. And when would you say that
7 you've done that?

8 A. I did that in 2006.

9 Q. Is that the one that you did
10 at the Mountainside Hospital?

11 A. That's correct.

12 Q. All right. Would it be --
13 withdrawn.

14 Do you have any materials or
15 did you provide any materials at the time
16 of that grand rounds, like a presentation
17 or handouts or anything?

18 A. I had a PowerPoint
19 presentation.

20 Q. Do you think that you still
21 have that PowerPoint presentation?

22 A. Highly possible, yes.

23 Q. If -- let me ask you this
24 question: If you had that PowerPoint

1 presentation, where do you think you
2 might have kept it or do keep it?

3 MR. ORENT: Objection.

4 THE WITNESS: I may have it
5 in one of my computers, yeah.

6 If I have a memory stick of
7 it, I -- that's another possibility,
8 although I don't know where the memory
9 stick is right now.

10 BY MR. TOMASELLI:

11 Q. Okay. Other than the grand
12 rounds in 2006 at Mountainside Hospital,
13 have you ever made any other public
14 presentations regarding the management of
15 stress urinary incontinence?

16 A. I've lectured to students.
17 Actually, correct that. I'm sorry. I've
18 lectured to residents, family practice
19 and internal medicine residents on topics
20 of this nature.

21 Q. Sorry. Where were those
22 residents engaged?

23 A. They were Mountainside
24 Hospital as well.

1 Q. Is that something you do --
2 try to do often or --

3 A. I enjoy teaching, so I do.

4 Q. Do you think that's
5 something you've done recently?

6 A. Probably in the last several
7 years, yes.

8 Q. And when you do that, when
9 you lecture to the residents, do you have
10 a set of materials, or is that more just
11 you talking?

12 A. It's usually a PowerPoint
13 presentation.

14 Q. And do you think that if you
15 looked around, that you might be able to
16 find those presentations?

17 MR. ORENT: Objection.

18 THE WITNESS: Highly
19 possible. Highly likely, yeah.

20 BY MR. TOMASELLI:

21 Q. My understanding is that
22 you're the Hackensack chief of the
23 department of surgery?

24 A. That's correct. Well, it

1 should say Hackensack UMC Mountainside.

2 It's one of the satellite hospitals of
3 Hackensack.

4 So there's a Hackensack
5 University Medical Center in Hackensack
6 that has its own chairman of surgery.
7 I'm the chairman of surgery at HUMC
8 Mountainside as it's called.

9 Q. Okay. Thank you for that
10 clarification.

11 And where is that hospital?

12 A. It's in Montclair, New
13 Jersey.

14 Q. Is it true that the
15 department of surgery at Hackensack
16 provides the highest quality clinical and
17 surgical care to its patients or it
18 attempts to?

19 A. I think it aspires to, yes.

20 Q. And does the hospital buy
21 the surgical devices related to urologic
22 surgeries in the hospital?

23 MR. ORENT: Objection.

24 THE WITNESS: It does.

1 BY MR. TOMASELLI:

2 Q. It does?

3 A. Yes.

4 Q. And do you know what devices
5 for stress urinary incontinence surgery
6 that they stock for their physicians?

7 A. Yes.

8 Q. Okay. And in terms of
9 midurethral slings made of polypropylene,
10 do you know which ones they stock?

11 A. Yes.

12 Q. And which ones are those?

13 A. Coloplast. And there may be
14 some -- may be some Boston Scientific
15 slings on -- as well.

16 Q. Any others?

17 A. I don't believe so today,
18 but I'm not 100 percent sure. I'm not --
19 you know, I'm not in central sterile
20 supply checking, but...

21 Q. Understand. But safe to say
22 the HUMC Mountainside Hospital does stock
23 midurethral slings for the treatment of
24 stress urinary incontinence that are made

1 of polypropylene?

2 MR. ORENT: Objection.

3 THE WITNESS: Yes.

4 BY MR. TOMASELLI:

5 Q. Have you ever done any
6 consulting for a pharmaceutical or
7 medical device company?

8 A. I have not.

9 Q. In your general opinion
10 number 1, Dr. Walmsley, you state that
11 "before a surgeon can inform a patient on
12 the risks/benefits/alternatives to any
13 procedure...the surgeon must be informed
14 on the risks/benefits/alternatives."

15 Do you see that?

16 A. I do.

17 Q. When we speak of stress
18 urinary incontinence surgery, what are
19 the different ways that a surgeon can
20 inform themselves on the risks, benefits
21 and alternatives of that?

22 MR. ORENT: Objection.

23 THE WITNESS: Well,
24 certainly one is through a review of

1 the IFU, the instructions for use.

2 The other may come in the form of the
3 experience one has had during their
4 training, during their residency and
5 fellowship.

6 From my standpoint, having
7 come out of my training in 2004, some
8 of my experience came with going to
9 training workshops that we discussed,
10 involving didactic and cadaveric
11 workshops and such.

12 And lastly, some of it is
13 based on clinical experience one has
14 in his or her private practice or
15 academic practice, as the case may be.

16 BY MR. TOMASELLI:

17 Q. Could physicians also gain
18 that information through conversations
19 with their colleagues in practice?

20 A. I think those can be
21 helpful, depending upon the colleague.

22 Q. I won't tell anybody.

23 Would some of that
24 information that surgeons can get come

1 from, for example, the medical
2 literature?

3 A. Yes.

4 Q. Would some of that
5 information, might it come also from
6 pronouncements or writings from the FDA?

7 MR. ORENT: Objection.

8 THE WITNESS: Not often, but
9 it can happen.

10 BY MR. TOMASELLI:

11 Q. Would some of that
12 information possibly come from
13 recommendations or practice guidelines
14 from national organizations?

15 MR. ORENT: Objection.

16 THE WITNESS: To some
17 degree, yes.

18 BY MR. TOMASELLI:

19 Q. Would some of that
20 information also come from potentially
21 attending national meetings, for example,
22 of the Urological Association?

23 MR. ORENT: Objection.

24 THE WITNESS: Yes.

1 BY MR. TOMASELLI:

2 Q. Because there are
3 presentations and posters and abstracts
4 and lectures and things like that?

5 A. Yes.

6 Q. And would you say that you
7 have accumulated knowledge over your
8 career about stress urinary incontinence
9 procedures and their outcomes and
10 complications, that you've gained
11 experience over the years?

12 A. This is true.

13 Q. Would you also say that
14 you've accumulated knowledge over the
15 years about when and what patients those
16 procedures might be more likely to fail
17 or might be more likely to be associated
18 with a complication?

19 A. Yes.

20 Q. In performing surgery on
21 your patients for stress urinary
22 incontinence, would you consider and draw
23 or try to draw from all the experience
24 that you've gained over the years from

1 those variety of sources of information?

2 A. Yes.

3 Q. And would you expect that --

4 each surgeon to do the same, that is, to

5 draw from the information and the

6 experience that they've been exposed to?

7 A. I would imagine that would

8 be reasonable.

9 Q. Do you, Dr. Walmsley, hold
10 yourself out as an engineer of any type?

11 A. No.

12 Q. Do you hold yourself out as
13 an anesthesiologist?

14 A. No.

15 Q. Do you hold yourself out as
16 a pain specialist?

17 A. Not in the sense of a pain
18 specialist under the anesthesia umbrella,
19 no.

20 Q. Have you ever drafted a
21 label for a medical device or a
22 medication?

23 A. I have not.

24 Q. Have you ever consulted with

1 a company regarding language, whether it
2 should be in or not in a particular
3 label?

4 A. Not that I can recollect,
5 no.

6 Q. Makes sense since you
7 haven't consulted with medical device or
8 pharmaceutical companies?

9 MR. ORENT: Objection.

10 THE WITNESS: I've not, but
11 I've been involved in the marketing
12 end of things, where companies will
13 come and show me different schemas and
14 advertisements for different products,
15 and I'll give feedback as to what I
16 think is perhaps more conducive or
17 relevant to what a physician wants to
18 see and things of that nature.

19 BY MR. TOMASELLI:

20 Q. And do you recall which
21 products that you've done that with?

22 A. Well, there have not been --
23 to my recollection, they've not been
24 medical device products, they've mostly

1 been medications.

2 Q. Are those for overactive
3 bladder?

4 A. Some of them, yeah.

5 Q. Outside of litigation, have
6 you ever communicated to a company that
7 their labeling -- to a medical device
8 company that their labeling was
9 inadequate?

10 A. Labeling regarding what
11 exactly?

12 Q. A medical device used for
13 stress urinary incontinence.

14 A. I've never given any advice
15 regarding labeling for an SUI product
16 outside of litigation.

17 Q. Have you ever read the FDA
18 regulations pertaining to the labeling of
19 medical devices?

20 A. Indirectly I have.

21 Q. And when you say indirectly,
22 what do you mean by that?

23 A. Well, when I first became
24 involved in some of the litigation that

1 you and I are involved with today, I did
2 review some of that. I mean, scratching
3 the surface type of stuff.

4 Q. Let's -- prior to becoming
5 retained in litigation, did you ever have
6 the occasion to go and read the FDA
7 regulations pertaining to medical
8 devices?

9 A. No.

10 Q. Have you ever worked or been
11 employed by the FDA?

12 A. I've not.

13 Q. Have you ever been asked by
14 the FDA to consult with respect to any
15 aspect of a medical device?

16 A. No.

17 Q. You said in your report that
18 you were trained on the TVT device.

19 Were you referring to that
20 being in your residency and fellowship?

21 A. Primarily my fellowship and
22 a little bit of residency. More exposure
23 in fellowship.

24 - - -

1 (A recess was taken from
2 12:50 p.m. to 1:06 p.m.)

3 - - -

4 BY MR. TOMASELLI:

5 Q. Dr. Walmsley, we took a
6 short break, and before that, we were
7 talking about your training with respect
8 to the TVT device.

9 Do you remember that?

10 A. Yes, sir.

11 Q. I'm marking as Deposition
12 Exhibit Number 3 a surgeon's resource
13 monograph related to the TVT device.

14 - - -

15 (Deposition Exhibit No.
16 Walmsley-3, Surgeon's Resource
17 Monograph, Bates stamped
18 ETH.MESH.10027307 through
19 ETH.MESH.10027328, was marked for
20 identification.)

21 - - -

22 BY MR. TOMASELLI:

23 Q. Do you see that?

24 A. I do.

1 Q. Do you remember ever
2 receiving this document?

3 A. I have seen this in past.

4 Q. All right. And with respect
5 to yourself or other surgeons who saw it,
6 would you agree that the information
7 contained in it could then be
8 incorporated into a, you know,
9 risk/benefit idea pertaining to the TVT
10 device itself?

11 MR. ORENT: Objection.

12 THE WITNESS: You mean for
13 those that have seen this?

14 BY MR. TOMASELLI:

15 Q. Yes, sir.

16 A. It could be helpful.

17 Q. Again, they could read it,
18 and that information could be
19 incorporated into their thinking?

20 A. Yes.

21 Q. All right. And to be clear,
22 Dr. Walmsley, the TVT SECUR midurethral
23 sling is made of Prolene, which is the
24 same material that the TVT retropubic

1 device is made from, and that's your
2 understanding. Right?

3 MR. ORENT: Objection.

4 THE WITNESS: That's a
5 polypropylene device.

6 BY MR. TOMASELLI:

7 Q. Yes, sir.

8 A. Yes.

9 Q. And it uses the trade name
10 Prolene, polypropylene mesh, in both the
11 TVT retropubic device that's talked about
12 in this document as well as the TVT
13 SECUR?

14 MR. ORENT: Objection.

15 THE WITNESS: Correct.

16 BY MR. TOMASELLI:

17 Q. Your general opinion number
18 1 again relates to the information
19 contained in the IFU for the TVT SECUR as
20 of 2010. Right?

21 A. Right.

22 Q. Okay. My understanding is
23 that the basis for your opinions in
24 general opinion number 1 come from,

1 number one, the fact that you read the
2 TVT SECUR IFU?

3 A. Correct.

4 Q. I think you also reference
5 your experience in this section. If you
6 go down to the bottom of this page, "In
7 my experience" with "dealing."

8 A. That speaks to talking about
9 mesh-induced foreign body response.

10 Q. Okay. But in terms of your
11 opinion regarding general opinion number
12 1, your experience plays into your
13 opinions? I'm asking if that's part of
14 your basis.

15 A. Could you repeat your
16 question? I'm not clear as to the nature
17 of it.

18 Q. So let me back up.

19 A. Uh-huh.

20 Q. General opinion number 1
21 states that it's your opinion that the
22 IFU for the TVT SECUR in 2010 was not
23 sufficient to enable informed consent?

24 A. That's correct.

1 Q. Okay. That's based upon,
2 number one, your reading of the TVT IFU?

3 A. That's based solely on my
4 reading of the TVT IFU, yes.

5 Q. Okay.

6 A. Yeah.

7 Q. No other basis for that
8 opinion?

9 MR. ORENT: Objection.

10 THE WITNESS: Well, I mean,
11 I think to some degree the basis of
12 that opinion comes -- is borne out of
13 the fact of the complications and
14 adverse events that do occur, they
15 aren't specifically spoken towards in
16 the IFU. So when you asked me, for
17 example, when I said "in my
18 experience," that supports my opinion
19 regarding the insufficiency of the TVT
20 SECUR IFU.

21 BY MR. TOMASELLI:

22 Q. You also reference a medical
23 dictionary pertaining to the words
24 "transitory" and "transient"?

1 A. Correct.

2 Q. All right. So in terms of
3 the IFU label, your experience that you
4 are drawing from in evaluating that and
5 the medical dictionary for the terms
6 "transient" and "transitory," are there
7 other bases for your opinion that you
8 came to in general opinion number 1?

9 A. Not specifically, no.

10 Q. In general opinion number 1,
11 you take issue, obviously, with the word
12 "transient" and "transitory" that are in
13 the TVT SECUR IFU. Right?

14 A. That's correct.

15 - - -

16 (Deposition Exhibit No.

17 Walmsley-4, Gynecare TFT SECUR

18 System IFU, Bates stamped

19 ETH.MESH.02340568 through

20 ETH.MESH.02340590, was marked for
21 identification.)

22 - - -

23 BY MR. TOMASELLI:

24 Q. And Exhibit 4 is the IFU for

1 the TVT SECUR. Right?

2 A. Yes.

3 Q. Is there anything else in
4 this IFU that you do not think is
5 accurately set forth? I know you have
6 opinions regarding omissions, and we'll
7 get there. But in terms of things that
8 are not accurately set forth, like the
9 word "transient" or "transitory," are
10 there other things?

11 A. With the exception of what
12 I've talked about in adverse reactions in
13 my general opinion, there really is
14 nothing else here that I'm critical of.

15 Q. Okay. In your general
16 opinion number 1, you state that the --
17 well, withdrawn.

18 With respect to your last
19 answer, that you -- that there's nothing
20 else that you're critical of, in terms of
21 the adverse reactions, you're critical of
22 the fact that they -- that it talks about
23 transitory local irritation and a
24 transitory foreign-body response. Right?

1 A. That's right.

2 Q. Otherwise, the adverse
3 reactions are accurate, in your mind?

4 A. No.

5 Q. They're not?

6 A. No. That's not correct.

7 Q. Okay. Why are they not
8 accurate?

9 A. In large part, because there
10 are several additional potential adverse
11 reactions that I believe I elucidate in
12 the following page.

13 Q. Right. And I'm going to
14 come to the things that you think should
15 also be in there.

16 A. Okay.

17 Q. I guess what I was getting
18 toward was you take issue with the
19 accuracy of the words "transitory" --

20 A. Correct.

21 Q. -- and "transient." Right?

22 A. Right.

23 Q. Is there anything else that
24 you take issue with the accuracy of?

1 A. As far as the five adverse
2 reactions listed in the IFU?

3 Q. Yes, sir.

4 A. Well, I mean, I think that
5 the first one, which is "Punctures or
6 lacerations or injury to vessels, nerves,
7 bladder, urethra, or bowel may occur
8 during instrument passage and may require
9 surgical repair," that to me is an
10 appropriately stated adverse reaction.

11 The second one, obviously I
12 take issue with the term "transitory,"
13 because typically the foreign-body
14 response is certainly neither transient
15 nor transitory.

16 And the second concern I
17 have regarding that particular bullet
18 point is the lack of context relating to
19 extrusion, erosion, fistula formation or
20 inflammation as it relates to treatment.

21 I mean, for example, in this
22 document, there's actually a lot more
23 language about what a surgeon in the
24 trenches might need to do to handle that,

1 whereas in the IFU here it's really not
2 elaborated on.

3 Q. And when you talk about that
4 these items in the IFU are elaborated in
5 a different document, you were holding
6 up --

7 A. I was holding up the --

8 Q. Exhibit Number 3, the
9 Surgeon's Resource Monograph?

10 A. Correct. Right.

11 Q. Again, anything else that
12 you say is actually not accurate in these
13 statements?

14 A. No.

15 Q. All right. With respect to
16 the next page, you state that the IFU
17 does not include the words, for example,
18 "mesh contraction" or "mesh shrinkage."
19 Correct?

20 A. Correct.

21 Q. And it's your opinion they
22 should have?

23 A. That's correct.

24 Q. All right. And in terms of

1 the clinical consequences of the mesh
2 contracting or the mesh shrinking, would
3 that include things like pain with
4 intercourse?

5 A. That could be one, yes.

6 Q. Would it include things like
7 pelvic pain?

8 A. That's correct.

9 Q. Would those be the most
10 common clinical consequences of mesh
11 contraction or mesh shrinkage?

12 A. Not completely, but some of
13 them.

14 Q. Can you identify other
15 clinical consequences that you would
16 identify with that?

17 A. Yes.

18 Q. Sure. Go ahead.

19 A. Voiding dysfunction.
20 Vaginal shortening. Kind of --
21 scar-plate formation, which is kind of a
22 part of -- to some degree part of mesh
23 contraction, but is related to that in
24 certain instances.

1 Q. And in terms of scar-plate
2 formation, what's the clinical
3 consequence of -- what does a patient
4 feel from scar-plate formation?

5 A. Well, it depends on, for
6 example, if they're sexually active,
7 they'll feel it more. Sometimes they'll
8 feel it simply from the standpoint of
9 having pain related to that phenomenon.
10 But the important reality to keep in mind
11 is that the vagina is a dynamic organ.
12 There are studies that demonstrate that
13 vaginal length can expand by up to
14 50 percent or more during stimulation,
15 for example. And the presence of
16 scar-plate formation, particularly if
17 there is a mesh response involved, an
18 untoward mesh response, that that can
19 exacerbate that problem.

20 Q. And would that -- would what
21 you just described in the last answer,
22 would that apply to all midurethral
23 slings made of polypropylene mesh?

24 MR. ORENT: Objection.

1 THE WITNESS: Well,

2 possibly, yeah.

3 BY MR. TOMASELLI:

4 Q. Could it also possibly apply
5 to biologic graft material?

6 A. Much less so.

7 Q. But it could possibly?

8 A. Theoretically.

9 Q. You state that the IFU does
10 not warn about the difficulty of removing
11 mesh; is that right?

12 A. That's correct.

13 Q. Do you agree that the design
14 of the midurethral sling with
15 polypropylene mesh is such that that mesh
16 will incorporate into the surrounding
17 tissue?

18 A. It's meant to.

19 Q. Is that also the same with
20 respect to autologous fascia and biologic
21 grafts, that you expect those materials
22 to incorporate into the surrounding
23 tissue?

24 A. In a different fashion, but

1 yes.

2 Q. Are any of the devices, a
3 midurethral sling made of polypropylene,
4 a biologic graft, an autologous fascia or
5 other devices, are they meant to be
6 permanent?

7 A. They're intended to be,
8 yeah.

9 Q. Is it true that surgeons
10 operating in this space and using those
11 devices understand that they're permanent
12 devices?

13 A. Yeah, I believe so. Yes.

14 Q. I think you also state in
15 your general opinion number 1 that the
16 IFU does not warn of dyspareunia. Right?

17 A. That's correct.

18 Q. And you think it should?

19 A. I do.

20 Q. All right. And we talked a
21 little bit about dyspareunia before.
22 Right?

23 A. Yes.

24 Q. And is it true, again, that

1 dyspareunia can actually pre-exist a
2 surgery, a stress urinary incontinence
3 surgery?

4 A. True.

5 Q. And it's true that
6 dyspareunia can come about or be new
7 after a stress urinary incontinence
8 surgery?

9 A. True.

10 Q. And I suppose the other
11 possibilities are that pre-existing
12 dyspareunia could get worse, or, as you
13 mentioned, the possibility of it getting
14 better?

15 MR. ORENT: Objection to
16 form.

17 BY MR. TOMASELLI:

18 Q. Possibly?

19 A. Yeah. All true.

20 Q. And would you say the same
21 thing for, for example, pelvic pain,
22 that, again, it could pre-exist or become
23 new after a stress urinary incontinence
24 surgery?

1 A. True.

2 Q. If you could turn to
3 Exhibit 4. I think you're with me.

4 A. Uh-huh.

5 Q. Do you see where there's a
6 page about warnings and precautions? It
7 might be one back or so from where you
8 are.

9 A. I do.

10 Q. Maybe a couple back.

11 Do you see that?

12 A. I do.

13 Q. All right. Do you see the
14 third bullet where it says, "Users should
15 be familiar with surgical technique for
16 urethral suspensions and should be
17 adequately trained in the GYNECARE TVT
18 SECUR System before using"?

19 A. I do.

20 Q. And when you read that users
21 should be familiar with urethral
22 suspension surgical techniques, what does
23 that mean to you as a surgeon?

24 A. What that means is that if

1 I'm coming into this space, interested in
2 using, let's say, the TVT SECUR product,
3 I should do so having a foundation of
4 knowledge having performed other urethral
5 suspension surgeries before embarking on
6 training in these procedures.

7 Q. When you talk about the
8 surgeries themselves, what types of
9 surgeries are you thinking about?

10 MR. ORENT: Objection.

11 THE WITNESS: Well, I mean,
12 I don't know. It's a fairly general
13 comment. Surgical technique for
14 urethral suspensions, I mean, that
15 could include Burch, MMK procedures.
16 That could include prior midurethral
17 sling procedures. So it's a bit of a
18 generic statement, to be fair.

19 BY MR. TOMASELLI:

20 Q. Sure. And could it -- I
21 mean, if you read that, could you also --
22 that could include autologous fascia or
23 biologic grafts as well?

24 A. It could.

1 Q. And when it says -- well,
2 withdrawn.

3 And when it says that you
4 should -- users should be familiar with
5 these, again, how does a surgeon become
6 familiar with those procedures such as
7 the Burch, the MMK, autologous fascia?
8 Can you describe how a surgeon would
9 become familiar with those?

10 A. Well, I mean, I can describe
11 how I became familiar with them.

12 Q. Okay.

13 A. And that was through my
14 training, through training in which I was
15 an apprentice/resident, seeing my
16 attendings perform these procedures,
17 getting involved with them as an
18 assistant and then finally kind of
19 executing them with my attendings
20 supervising me.

21 Q. And would you also, again,
22 gain information -- I guess in those
23 various things we talked about earlier,
24 would you gain information about those

1 surgical procedures in the same way?

2 A. I think to some degree, yes.

3 Q. Okay. By the way, who was
4 your -- who did you train under as a
5 fellow?

6 A. In my residency -- in my
7 fellowship I was under a gentleman named
8 Steven Kaplan.

9 Q. Is that with a K?

10 A. Yeah, K-A-P-L-A-N, Steven.

11 Q. And who did you train under
12 as a resident in urologic surgery?

13 A. My residency with regards to
14 female urology, slings and such, I
15 trained under a gentleman named George
16 Young, Jerry Blaivas, and David Staskin,
17 S-T-A-S-K-I-N. And Blaivas is
18 B-L-A-I-V-A-S, or V-I-S or A-S.

19 Q. Did you find that all those
20 surgeons were well informed and good at
21 what they did?

22 A. I felt like they were.

23 Q. Would you say that you
24 learned a lot from them?

1 A. A lot, yes.

2 Q. When we talk about general
3 opinion number 2 in your report, that's
4 the one that references the autologous
5 fascia as a safer alternative design in
6 2010 to the TVT SECUR.

7 Do you remember that?

8 A. Correct.

9 Q. In the first sentence,
10 Dr. Walmsley, you state that these
11 designs and procedures existed in 2010
12 that have a less risk of erosion and
13 dyspareunia, which I'll get to, but you
14 also say that they have substantially
15 equivalent efficacy.

16 Do you see that?

17 A. Correct, yes.

18 Q. Okay. Are you saying there
19 that, for example, the autologous fascial
20 sling has equivalent efficacy in terms of
21 curing stress urinary incontinence, are
22 you saying it has equivalent efficacy to
23 the TVT SECUR?

24 A. In this document, yes.

1 Q. Okay. And is that your
2 opinion, that the TVT SECUR had
3 equivalent efficacy, for example, to the
4 autologous fascial sling?

5 A. I think it's a little bit of
6 an apples to oranges comparison in part
7 because there's a richer or more
8 prevalent amount of literature for the
9 autologous slings compared to the TVT
10 SECUR, because the TVT SECUR was really
11 only on the market for only a brief
12 period of time, so...

13 And the follow-up on a lot
14 of the studies for TVT SECUR were
15 somewhat short comparatively to the
16 autologous fascial sling. But generally
17 speaking, I would hold that to be true.

18 Q. Did you go and try to search
19 for all the TVT SECUR literature from,
20 say, 2005 up to 2010 and see what there
21 was out there?

22 A. I've looked at some of that
23 literature.

24 Q. All right. There are, in

1 fact, studies that are published
2 regarding the TVT SECUR prior to 2010
3 that have outcomes up to a year or more?

4 A. I thought I --

5 MR. ORENT: Objection.

6 THE WITNESS: I thought I
7 saw a year, 18 months.

8 BY MR. TOMASELLI:

9 Q. Okay.

10 A. But to be fair, there are
11 also autologous fascial slings that have
12 five, five-year data and so forth.

13 Q. In terms of the -- maybe the
14 one-year outcomes, is that more apples to
15 apples?

16 A. Yeah. We can compare one
17 year/one year for each.

18 Q. When you say that the
19 autologous fascial sling had
20 substantially equivalent efficacy, would
21 you say that maybe at the year point, the
22 autologous fascial sling had
23 substantially equivalent efficacy to the
24 TVT SECUR?

1 MR. ORENT: Objection.

2 THE WITNESS: I would say
3 that.

4 BY MR. TOMASELLI:

5 Q. Is that a yes?

6 A. I would say yes.

7 Q. In your general opinion
8 number 2, you say that the autologous
9 fascial sling has a less risk of erosion
10 than the TVT SECUR.

11 What's your basis for that
12 statement?

13 A. My clinical experience and
14 the literature surrounding TVT SECUR
15 compared to autologous fascial slings.

16 Q. When you reference the
17 literature surrounding autologous slings
18 and the TVT SECUR, are you referencing
19 studies that have them head to head or
20 the general body of literature for both?

21 A. The latter. I don't know of
22 any head-to-head studies comparing the
23 two myself.

24 Q. That was my next question.

1 A. Yeah.

2 Q. Dr. Walmsley, maybe we'll
3 get that one out.

4 A. Right.

5 Q. Withdrawn.

6 Dr. Walmsley, are you aware
7 of any head-to-head studies between the
8 TVT SECUR and the autologous fascial
9 sling using rectus fascia?

10 A. I'm not.

11 Q. When you say in your general
12 opinion number 2, Dr. Walmsley, that the
13 TVT SECUR has a higher rate of
14 dyspareunia than the autologous fascial
15 sling using rectus fascia, what's the
16 basis for your opinion?

17 A. Once again, a review of the
18 literature that gives dyspareunia rates
19 for each of those techniques, and to some
20 degree, although I've never had clinical
21 experience with TVT SECUR implanting it,
22 I've seen patients implanted with TVT
23 SECUR that have had complaints of
24 dyspareunia.

1 Q. And what would you
2 approximate the rate of dyspareunia for
3 the TVT SECUR as opposed to the rate of
4 dyspareunia for the autologous fascial
5 sling based on the literature? Do you
6 have numbers in mind? That's my
7 question.

8 A. Yeah. I mean, I think based
9 on autologous fascial sling, you're
10 talking maybe 1 to 3 percent, whereas for
11 TVT SECUR you're looking at somewhere in
12 the high single digits. But I mean,
13 think, once again, to be -- to give a
14 completely thorough answer, one has to
15 really talk about the nature of the
16 dyspareunia. I mean, not all dyspareunia
17 is created equal. And certainly in my
18 clinical experience, and the literature
19 would speak to this, perhaps not
20 specifically for TVT SECUR, but perhaps
21 it's a different kind of dyspareunia.

22 Q. And the different kind of
23 dyspareunia that you're referencing,
24 would that also apply to other

1 midurethral slings made of polypropylene
2 mesh?

3 A. To some degree, yes.

4 Q. When you say to some degree,
5 what do you mean?

6 A. Well, once again, I think
7 when you're looking at literature or
8 peer-reviewed journals that talk about
9 dyspareunia, it's sometimes one's
10 definition of dyspareunia can be
11 different. Sometimes the questions
12 aren't asked, do you have dyspareunia,
13 for example. So I think to really give a
14 hard and fast objective, let's say,
15 number, it's a bit misleading.

16 What I can tell you in my
17 clinical experience is that if I've
18 encountered dyspareunia in an autologous
19 fascial sling, which is exceedingly rare,
20 it tends to be something that's mild,
21 something that can be treatable, for
22 example, with vaginal estrogen, where in
23 the TVT SECUR setting, I have encountered
24 a handful of patients, less than five,

1 but memorable patients, where the
2 scarring and healing process inherent to
3 that device, you know, not only renders
4 them with dyspareunia but the kind of
5 pain that you can reproduce on an exam
6 where you're feeling -- we call it
7 indurated tissue, but heavily scarred-in
8 tissue that's undergone a very intense
9 response to the implant.

10 So that's why I think you
11 can say a percentage number, but I don't
12 think the percentage number necessarily
13 gives a full meaning.

14 Q. All right. So if I
15 understand your opinion in general
16 opinion number 2 is that the lesser risk
17 of erosion with an autologous sling you
18 would say is both lower in terms --
19 withdrawn. Let me try this again.

20 Dr. Walmsley, if I
21 understand your opinion in general
22 opinion number 2 regarding dyspareunia,
23 it's that when you compare the TVT SECUR
24 to the autologous fascia, there's not

1 only a numerical less risk with
2 dyspareunia, but the dyspareunia is of a
3 different character?

4 A. Correct.

5 Q. In terms of the less risk of
6 erosion between the TVT SECUR and the
7 autologous fascia, where are you
8 discussing the erosion, by the way? Is
9 that erosion into any organ?

10 A. Yeah. That would fall under
11 that category.

12 Q. And in terms of, again,
13 putting -- if you put a number on the
14 less risk that you believe is with an
15 autologous sling compared to the TVT
16 SECUR, can you try to do that based on
17 your review of the literature?

18 A. I can.

19 Q. Can you do that?

20 A. The most recent Cochrane
21 analysis -- this is a reliance list or a
22 piece of information that I've recently
23 reviewed that is not in this particular
24 document -- the rate was about 12 percent

1 with synthetics, TVT SECUR falling under
2 that category; whereas for autologous,
3 it's in the order of 1 to 2 percent.

4 Q. And when you reference this
5 Cochrane analysis, do you recall the
6 first author of that? Is that Ford?

7 A. It's either Ford or --

8 Q. Oga?

9 A. Ott maybe. I have it in my
10 computer, but I don't remember
11 specifically who it is. But it's a 2016
12 Cochrane review report.

13 Q. Are there adverse events in
14 that Cochrane report that are more common
15 with autologous slings than with TVT
16 midurethral slings?

17 A. Once again, this wasn't a
18 comparison of the two. This was looking
19 at -- that 12 percent is off that
20 Cochrane review. The 2 percent is more
21 of an amalgamation of my readings of
22 other autologous fascial sling reviews.
23 So they aren't comparing one and the
24 other, to be fair.

1 Q. Okay. And I think we
2 established this, but you're not aware of
3 any randomized clinical trial comparing
4 an autologous rectal fascial sling to the
5 TVT SECUR?

6 A. I'm not.

7 Q. And you're not aware of any
8 observational study, whether prospective
9 or retrospective, comparing the
10 autologous fascial slings to the TVT
11 SECUR?

12 A. I'm not.

13 Q. Based on your review of the
14 literature, would you say that there are
15 any complications with respect to the
16 autologous rectal fascial slings that are
17 more common than you would otherwise see
18 in a TVT midurethral sling?

19 A. There are a couple.

20 Q. Can you describe those for
21 me?

22 A. One is the fact that you're
23 harvesting fascia, so you're making an
24 additional incision. I don't know if

1 that's an adverse event or a
2 complication, but as a result of that,
3 there is temporarily at least more pain
4 related to that.

5 Q. Would you agree that urinary
6 retention is higher with respect to
7 autologous fascial slings than with the
8 TVT midurethral sling?

9 A. That can happen, yes.

10 Q. Would you agree there are
11 more wound complications, maybe because
12 of the harvesting, with respect to
13 autologous fascial slings than the TVT
14 devices?

15 A. That's a temporary
16 phenomenon that can occur, yes.

17 Q. Dr. Walmsley, in your expert
18 report that contains your materials
19 reviewed list, there are a series of
20 articles that you cite. Correct?

21 A. Yes.

22 Q. The first article I've
23 marked as Exhibit Number 5.

24 - - -

1 (Deposition Exhibit No.
2 Walmsley-5, Article entitled "A
3 clinical and urodynamic study
4 comparing the Stamey bladder neck
5 suspension and suburethral sling
6 procedures in the treatment of
7 genuine stress incontinence" by
8 Hilton, was marked for
9 identification.)

10 - - -

11 BY MR. TOMASELLI:

12 Q. Which is a paper by Hilton.

13 Do you see that?

14 A. I do, yep.

15 Q. And I don't know if you know
16 this off the top of your head.

17 MR. ORENT: Can I get a copy
18 of that?

19 MR. TOMASELLI: You may. So
20 withdrawn. I'll start a new question.

21 MR. ORENT: Thank you.

22 BY MR. TOMASELLI:

23 Q. Exhibit 5 is, indeed, the
24 Hilton paper. Correct?

1 A. Yes.

2 Q. And do you recall why you
3 cited this paper in connection with your
4 report?

5 A. Well, the -- to get an idea
6 of a comparison between a sling and this
7 endoscopic technique, which really, quite
8 frankly, doesn't occur much anymore.
9 That was the main intention.

10 Q. And the sling that was used
11 in this study was actually made of pig
12 graft?

13 A. Correct, yes.

14 Q. And if you turn to Table 6
15 of the paper on page 216 --

16 A. Uh-huh.

17 Q. -- there are a list of
18 complications; is that correct?

19 A. Yes.

20 Q. And so would you agree that,
21 again, physicians like yourself who are
22 reviewing these papers can look at the
23 operative and postoperative
24 complications, and it helps inform their

1 view as to what can possibly happen
2 during a stress urinary incontinence
3 surgery?

4 A. Yes.

5 - - -

6 (Deposition Exhibit No.
7 Walmsley-6, Article entitled
8 "Comparison of Burch and Lyodura
9 Sling Procedures for Repair of
10 Unsuccessful Incontinence
11 Surgery," by Enzelsberger, et al.,
12 was marked for identification.)

13 - - -

14 BY MR. TOMASELLI:

15 Q. Dr. Walmsley, I'm going to
16 hand you what I've marked as Deposition
17 Exhibit Number 6, which is a paper by
18 Enzelsberger from 1996.

19 Do you see that?

20 A. I do.

21 Q. And this is the second paper
22 in your materials reviews list?

23 A. Yes.

24 Q. And do you recall why you

1 decided to cite this particular paper in
2 your report?

3 A. I thought it would be
4 helpful to have a comparison, maybe
5 apples to oranges because of the fact
6 it's maybe an older study and maybe not
7 the same type of material, but comparing
8 Burch versus sling.

9 Q. And why is it that you
10 wanted to cite papers pertaining to a
11 comparison between the Burch procedure
12 and sling procedures?

13 A. I was trying to establish
14 the fact that there are different ways to
15 treat this condition and to educate
16 myself and certainly have it reflected in
17 my reports regarding the pros and cons of
18 each approach.

19 - - -

20 (Deposition Exhibit No.
21 Walmsley-7, Article entitled
22 "Burch Colposuspension versus
23 Fascial Sling to Reduce Urinary
24 Stress Incontinence," by Albo, et

1 al., was marked for
2 identification.)

3 - - -

4 BY MR. TOMASELLI:

5 Q. I'm going to mark as
6 Deposition Exhibit Number 7 the paper by
7 Albo and colleagues in the New England
8 Journal of Medicine from 2007.

9 Do you see that?

10 A. I do.

11 Q. Are you familiar with this
12 paper?

13 A. Vaguely. I remember reading
14 this paper.

15 Q. Because you said you were
16 interested in comparisons related to the
17 Burch procedure and autologous rectus
18 fascia, that's the reason I gave you this
19 paper. Okay?

20 A. Correct.

21 Q. All right.

22 A. Yeah.

23 Q. And, indeed, this is a large
24 randomized trial comparing the Burch

1 procedure to autologous rectal fascia?

2 A. Correct.

3 Q. And if we turn, for example,
4 to Table 2, and all the information below
5 Table 2, do you see where it talks about
6 a variety of adverse events?

7 A. I see the table, yes.

8 Q. And, indeed, that table does
9 talk about a variety of adverse events
10 that occurred within the trial?

11 A. Yes.

12 Q. All right. And surgeons
13 like yourself looking at medical
14 literature can find this as one place of
15 information to see what types of adverse
16 events other surgeons are encountering
17 during procedures for stress urinary
18 incontinence?

19 A. Fair.

20 Q. Coming back to Deposition
21 Exhibit Number 6, the Enzelsberger paper,
22 can you tell me when you have that?

23 A. I have it.

24 Q. Can you turn to page 254,

1 which has Table 3 in the upper right-hand
2 corner?

3 A. Yes.

4 Q. We talked previously about
5 the fact that patients can have urgency
6 symptoms and urge incontinence post or
7 after stress urinary incontinence
8 surgery; is that right?

9 A. Correct.

10 Q. And in Table 3, for example,
11 it talks about 8 percent of the patients
12 following Burch and 16 percent of the
13 patients following sling procedure had
14 urgency or urge incontinence.

15 Do you see that?

16 A. I do.

17 Q. Is that consistent with your
18 experience?

19 A. You know, my exposure to
20 Burches are a little limited. Certainly
21 with regards to the sling procedure, I
22 have a slightly lower experience, but
23 that's fairly representative.

24 Q. Okay. The next paper in

Konstantin Walmsley, M.D.

1 your report I couldn't find, so we'll go
2 to the next one, which is by Guerrero.

3 - - -

4 (Deposition Exhibit No.
5 Walmsley-8, Article entitled "A
6 randomised controlled trial
7 comparing two autologous fascial
8 sling techniques for the treatment
9 of stress urinary incontinence in
10 women: short, medium and
11 long-term follow-up" by Guerrero,
12 et al., was marked for
13 identification.)

14 - - -

15 BY MR. TOMASELLI:

16 Q. And I promise that I'm not
17 going to do this with all of them. All
18 right. Withdrawn.

19 Dr. Walmsley, I'm handing
20 you what I've marked as Deposition
21 Exhibit Number 8 --

22 A. Yep.

23 Q. -- which is a paper by
24 Guerrero and others which you cited in

1 your expert report; is that right?

2 A. Yep. Yes.

3 Q. And can you describe for me,
4 if you can, the reason, if you recall,
5 that you cited this paper in your expert
6 report?

7 A. Primarily to have a fairly
8 large core of patients, I mean, it's a
9 group of almost 100 -- 165 women who
10 received autologous fascial slings, the
11 intention being to get an idea of success
12 rates and things of that nature.

13 Q. And when you talk about the
14 type of sling that they received in this
15 Deposition Exhibit Number 8, that's the
16 type of sling that you referred to in
17 general opinion number 2?

18 A. Yes. Although the
19 techniques are -- there's a modification
20 on the technique that I don't currently
21 employ called sling on a string.

22 Q. Okay. And if we turn over
23 to page 1266, do you see that in the pros
24 portion of 1266 on the right-hand column,

1 there's a paragraph that starts, "Table 3
2 shows"?

3 A. You're on page 1266?

4 Q. 1266.

5 A. Yes.

6 Q. Do you see there's a
7 paragraph there that starts "Table 3
8 shows"?

9 A. I see that.

10 Q. Okay. It states, "As
11 expected, the baseline incidence is 100%
12 in both groups."

13 They're speaking of stress
14 urinary incontinence; is that right?

15 A. Yes, I see that.

16 Q. And the stress urinary
17 incontinence decreases to between 10 and
18 21 percent at three months.

19 Do you see that?

20 A. I see that.

21 Q. So would you interpret that
22 to mean that of all these patients that
23 are undergoing this stress urinary
24 incontinence surgery, between 10 and

1 21 percent, they continued to have some
2 stress urinary incontinence surgery --
3 stress urinary incontinence after their
4 surgery?

5 A. Yeah. I mean, in this
6 cohort of British women at this clinic,
7 that's the case.

8 Q. Okay. And then if we go
9 down, continuing in the paragraph, it
10 states that the -- the leakage, that is,
11 the stress urinary incontinence in the
12 women, continues to rise over time?

13 A. Correct.

14 Q. And by the long-term
15 follow-up, the incidence of leakage is at
16 best 38 to 43 percent, but could be as
17 high as 71 percent.

18 Do you see that?

19 A. I do see that.

20 Q. Okay. If you can turn over
21 a couple of pages to Table 6 at the
22 bottom of page 1268 and tell me when
23 you're there.

24 A. I'm here.

1 Q. Do you see that there's a
2 table talking about pain?

3 A. Yes.

4 Q. All right. And there's a
5 line or row that talks about how many
6 people had pain even three months after
7 operation; is that right?

8 A. Yes.

9 Q. And do you see that in these
10 two groups, 51 percent in one group and
11 67 percent in another group continue to
12 have pain three months after surgery?

13 A. I see that.

14 Q. All right. And again, in
15 terms of above Table 6, up into Table 5
16 on the same page, there's a description
17 of complications. Right?

18 A. Yes.

19 Q. And surgeons like yourself
20 reading these articles can look at
21 complications and see what other surgeons
22 have encountered with respect to stress
23 urinary incontinence procedures?

24 A. They can use this as a

1 resource, yes.

2 Q. The -- if you look back to
3 your report, Doctor, where we were moving
4 down the articles, do you see that the
5 next article that you reference in your
6 report is by Welk?

7 A. Yes.

8 Q. And tell me if I'm wrong,
9 but it looks like the remainder of the
10 articles that you talk about in your
11 report deal more with complications
12 following midurethral sling placement.
13 Is that fair?

14 A. Yeah, that's correct.

15 Q. Are there any other articles
16 that you cite --

17 A. May I just --

18 Q. Yeah, yeah, sure.

19 A. The Petri and Klosterhalfen
20 are two that really don't, but you're
21 talking about Anger, from Anger on is
22 where those are really more of the
23 complication-based references. Is that
24 what you said?

1 Q. Even Petri, you know, the
2 title is "Complications of synthetic
3 slings"?

4 A. Yeah. It's just that --
5 yeah, I guess Klosterhalfen is not
6 specifically a complication one, per se,
7 but the others are. Yes.

8 Q. Okay. I guess Moalli
9 actually relates to the properties of
10 mesh as well?

11 A. Correct, yeah.

12 Q. I guess my question is this:
13 Other than the papers that we talked
14 about and the one that I couldn't get on
15 porcine dermal sling, are there other
16 papers that are in the top of your head
17 that you're relying on for your opinions
18 in this case?

19 A. In this case, what's stated
20 in the report is what's reflective of my
21 opinions in the report.

22 MR. TOMASELLI: Okay. I
23 will tell you what, can we go off the
24 record for just a minute.

1 MR. ORENT: Sure.

2 MR. TOMASELLI: I'm going to
3 try to finish real quick. Okay? So
4 if you've just got 2 or 3 minutes, I'm
5 going to look at my stuff.

6 - - -

7 (A recess was taken from
8 1:52 p.m. to 1:58 p.m.)

9 - - -

10 BY MR. TOMASELLI:

11 Q. Dr. Walmsley, are you ready?

12 A. Yes, sir.

13 Q. Dr. Walmsley, we took a
14 quick break, and are you ready to
15 proceed?

16 A. I am.

17 Q. Great. I'm handing you what
18 I've marked as Deposition Exhibit Number
19 9.

20 - - -

21 (Deposition Exhibit No.
22 Walmsley-9, AUA Position Statement
23 on the Use of Vaginal mesh for the
24 Surgical Treatment of Stress

1 Urinary Incontinence (SUI), was
2 marked for identification.)

3 - - -

4 BY MR. TOMASELLI:

5 Q. And this is a "Position
6 Statement on the Use of...Mesh for the
7 Treatment of Stress Urinary Incontinence"
8 from the American Urological Association.

9 Do you see that?

10 A. I do.

11 Q. And you told me that you're
12 a member of the AUA?

13 A. I am.

14 Q. Okay. Have you seen this
15 before?

16 A. I have.

17 Q. And do you agree with the
18 position statement of the American
19 Urological Association?

20 MR. ORENT: Objection.

21 THE WITNESS: In part I
22 agree, yes.

23 BY MR. TOMASELLI:

24 Q. Okay. Do you agree that

1 with -- withdrawn.

2 Do you agree with the

3 statements -- statement that --

4 withdrawn.

5 Do you agree with the

6 association statement that "Extensive

7 data exist to support the use of

8 synthetic polypropylene mesh suburethral

9 slings for the treatment of female stress

10 urinary incontinence, with minimal

11 morbidity compared with alternative

12 surgeries"?

13 MR. ORENT: Objection.

14 THE WITNESS: I do agree

15 with that.

16 BY MR. TOMASELLI:

17 Q. Do you agree with the next

18 sentence that "Advantages include shorter

19 operative time/anesthetic need, reduced

20 surgical pain, reduced hospitalization,

21 and reduced voiding dysfunction"?

22 MR. ORENT: Objection.

23 THE WITNESS: I do.

24 BY MR. TOMASELLI:

1 Q. Do you agree that
2 "Mesh-related complications can occur
3 following polypropylene sling placement,
4 but the rate of...complications is
5 acceptably low"?

6 MR. ORENT: Objection.

7 THE WITNESS: Not exactly.

8 BY MR. TOMASELLI:

9 Q. But it is true that today
10 you continue to use polypropylene
11 midurethral slings for the treatment of
12 stress urinary incontinence?

13 A. In the context of proper
14 informed consent, I do, yes.

15 Q. Okay. Do you agree that "it
16 is important to recognize that many
17 sling-related complications are not
18 unique to mesh surgeries and are known to
19 occur with non-mesh sling procedures as
20 well"?

21 A. I think, once again, from a
22 quantitative statement, yes. From a
23 qualitative standpoint, there needs to be
24 a proper discussion with patients.

1 Q. Have you ever written the
2 American Urological Association and noted
3 any disagreement with this position
4 statement?

5 A. I never write to the AUA.

6 Q. Did you ever provide any
7 comments to this position statement?

8 A. I talked to my colleagues
9 about it.

10 Q. Okay. And did you talk to
11 them about what we just talked about?

12 A. Yes, yeah.

13 Q. Do your colleagues, your
14 partners that you practice with, do they
15 also continue to place polypropylene
16 midurethral slings for the treatment of
17 stress urinary incontinence?

18 MR. ORENT: Objection.

19 THE WITNESS: Not all of
20 them.

21 BY MR. TOMASELLI:

22 Q. Some of them do?

23 MR. ORENT: Objection.

24 THE WITNESS: Some do.

1 BY MR. TOMASELLI:

2 Q. In terms of some of the
3 studies that we were just looking at, we
4 looked at a number of randomized clinical
5 trials.

6 Do you remember that?

7 A. We did look at some, yes.

8 Q. And you're familiar with
9 what a randomized clinical trial is?

10 A. Yes.

11 Q. Would you agree that it's
12 the highest level of evidence to compare
13 interventions in a particular indication?

14 A. I think it's very strong.

15 Q. Would you also agree that
16 systematic analyses of multiple
17 randomized trials are also a strong way
18 to look at data and compare
19 interventions?

20 A. I think they can be helpful,
21 yes.

22 Q. In your practice, do you
23 rely on randomized clinical trials and
24 systematic reviews of randomized clinical

1 trials to help inform your opinions and
2 judgments in your practice?

3 MR. ORENT: Objection.

4 THE WITNESS: Assuming that
5 I hold the evidence in high regard, I
6 do, yes.

7 BY MR. TOMASELLI:

8 Q. Looking at the papers --
9 withdrawn.

10 I think what you just said
11 is as long as you can read the paper and
12 are comfortable with the methods in the
13 randomized trial that's being done, you
14 would be comfortable taking those results
15 and putting them into the calculus, so to
16 speak, of your practice?

17 MR. ORENT: Objection.

18 THE WITNESS: I mean, I
19 think the construct of those types of
20 trials, randomized control trials,
21 systematic reviews, can be helpful,
22 assuming that the endpoints that are
23 looked at are relevant to me in my
24 practice. That's my point, yeah.

1 MR. TOMASELLI: I will pass
2 the witness at this point. And thank
3 you for your time.

4 THE WITNESS: Thank you.

5 - - -

6 EXAMINATION

7 - - -

8 BY MR. ORENT:

9 Q. Doctor, just a few questions
10 on Exhibit Number 9.

11 A. Yes.

12 Q. Would you agree with me,
13 Doctor, that this is not a scientific
14 statement?

15 MR. TOMASELLI: Objection,
16 leading.

17 THE WITNESS: This is a
18 position statement, that's correct.

19 BY MR. ORENT:

20 Q. And a position statement is
21 an advocacy piece. Correct?

22 MR. TOMASELLI: Objection to
23 form, leading.

24 THE WITNESS: Yeah, to some

1 degree that's correct.

2 BY MR. ORENT:

3 Q. And, Doctor, would you agree
4 that as a practitioner, you would not
5 blindly rely upon a position statement
6 like this for your choices in medical
7 care and treatment of your patients?

8 MR. TOMASELLI: Object to
9 form, leading.

10 THE WITNESS: This has no
11 impact on how I use mesh or did not
12 influence me in any way for my
13 presence or lack of presence to use
14 mesh.

15 BY MR. ORENT:

16 Q. And a doctor in your
17 situation, your position, a board
18 certified urologist who performs stress
19 urinary incontinence procedures, would a
20 urologist like yourself rely upon a
21 position statement like this for the
22 decision to use a device?

23 MR. TOMASELLI: Object to
24 form, asked and answered.

1 THE WITNESS: No.

2 BY MR. ORENT:

3 Q. Now, Doctor, this position
4 statement by AUA doesn't -- on the face
5 of it excludes mini slings,
6 single-incision mini slings like TVT-S;
7 isn't that right?

8 MR. TOMASELLI: Object to
9 form, leading.

10 THE WITNESS: Well, there's
11 no comment here regarding mini slings.
12 And for the record, I mean, this is a
13 statement that was published in 2011.

14 BY MR. ORENT:

15 Q. Let me just point out one
16 thing. "Additionally, both the Society
17 of Urodynamics" --

18 A. Uh-huh.

19 Q. Do you see where I am?

20 A. Yes.

21 Q. -- "Female Pelvic Medicine
22 and Urogenital Reconstruction (SUFU) and
23 the AUA support the use of multi-incision
24 monofilament midurethral slings for the

1 treatment of SUI in properly selected
2 patients who are appropriately counseled
3 regarding this this" -- there's a typo
4 there -- "surgical procedure by surgeons
5 who are trained in the placement of such
6 devices, as well as the recognition and
7 management of potential complications
8 associated with their use."

9 Did I read that correctly,
10 Doctor?

11 A. You did.

12 Q. Now, Doctor, that
13 specifically references multi-incision
14 slings; is that right?

15 A. Correct.

16 Q. And the TVT-S that you're
17 opining about today is not a
18 multi-incision sling; is that correct?

19 A. That's correct.

20 Q. And so by its very terms,
21 this statement does not apply to the
22 product that you are discussing here
23 today. Is that true?

24 MR. TOMASELLI: Object to

1 leading.

2 THE WITNESS: Based on that
3 statement, yes.

4 BY MR. ORENT:

5 Q. Okay. Now, Doctor, you
6 would agree with me that even for
7 multi-incision devices, this lumps them
8 all together?

9 A. It does.

10 Q. And would you agree, Doctor,
11 that not all multi-incision polypropylene
12 mesh slings are created equal?

13 MR. TOMASELLI: Object to
14 form, leading.

15 THE WITNESS: This is true.

16 BY MR. ORENT:

17 Q. And an example of that would
18 be Mentor's ObTape device is made of
19 polypropylene. Correct?

20 A. Yes.

21 Q. And it was a multi-incision
22 full-length sling. Correct?

23 A. Correct.

24 Q. It was a midurethral

1 transobturator sling. Correct?

2 A. Yes.

3 Q. And so theoretically, that
4 would be included under AUA's position
5 statement. Correct?

6 MR. TOMASELLI: Object to
7 form, leading.

8 THE WITNESS: That's
9 correct.

10 BY MR. ORENT:

11 Q. And, Doctor, would you agree
12 with me that no reputable doctor today
13 would support the safety and efficacy of
14 the Mentor ObTape?

15 MR. TOMASELLI: Leading.

16 THE WITNESS: That's
17 correct.

18 BY MR. ORENT:

19 Q. Similarly, each device at
20 issue -- excuse me, each device has
21 different amounts of data associated with
22 it. Correct?

23 A. True.

24 Q. Different devices have

1 different pore sizes. Correct?

2 A. Yes.

3 Q. And they have different
4 stiffness and other physical properties.
5 Correct?

6 MR. TOMASELLI: Object to
7 form, leading.

8 THE WITNESS: Yes.

9 BY MR. ORENT:

10 Q. And, Doctor, in your
11 professional opinion, do you believe that
12 a device needs to be evaluated on its own
13 merits as opposed to lumped together?

14 MR. TOMASELLI: Object to
15 form, leading.

16 THE WITNESS: Certainly,
17 yes.

18 BY MR. ORENT:

19 Q. And, Doctor, with -- if you
20 look at the last big paragraph, "Multiple
21 case series and randomized controlled
22 trials attest to the efficacy of
23 synthetic polypropylene mesh slings at
24 5-10 years," Doctor, are you, as you sit

1 here today, aware of any 10-year data on
2 the TVT-S?

3 A. I'm not.

4 Q. And, Doctor, are you aware
5 of any 5-year data on the TVT-S?

6 A. I'm not.

7 Q. And you performed a
8 literature search for each of those
9 items, did you not?

10 A. I did.

11 MR. ORENT: Thank you very
12 much, Doctor. I have no further
13 questions.

14 - - -

15 EXAMINATION

16 - - -

17 BY MR. TOMASELLI:

18 Q. Doctor, did you perform a
19 thorough literature search to see if
20 there was any 5-year randomized data with
21 respect to the TVT SECUR?

22 A. I couldn't find any in my
23 research, unless I missed something.

24 MR. TOMASELLI: I think

1 we're done here.

2 MR. ORENT: Excellent.

3 (Witness excused.)

4 (Deposition concluded at

5 approximately 2:11 p.m.)

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Konstantin Walmsley, M.D.

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CERTIFICATE

I HEREBY CERTIFY that the
witness was duly sworn by me and that the
deposition is a true record of the
testimony given by the witness.

It was requested before
completion of the deposition that the
witness, KONSTANTIN WALMSLEY, MD, have
the opportunity to read and sign the
deposition transcript.

ANN MARIE MITCHELL, a Federally
Approved Certified Realtime
Reporter, Registered Diplomate
Reporter and Notary Public

(The foregoing certification
of this transcript does not apply to any
reproduction of the same by any means,
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supervision of the certifying reporter.)

1 INSTRUCTIONS TO WITNESS

2

3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

21

22

23

24

Konstantin Walmsley, M.D.

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ACKNOWLEDGMENT OF DEPONENT

3

4

I, _____, do

5

hereby certify that I have read the

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foregoing pages, 1 - 131, and that the

7

same is a correct transcription of the

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substance, if any, noted in the attached

12

Errata Sheet.

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16

KONSTANTIN WALMSLEY, MD

DATE

17

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Subscribed and sworn

to before me this

21

_____ day of _____, 20____.

22

My commission expires:_____

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Notary Public

Konstantin Walmsley, M.D.

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